prevailed upon Schering to pay ESI $5 million, which he characterized as "nothing more than legal fees." Pet. App. at 7a. Next, Judge Rueter and Schering discussed a concept under which Schering would pay ESI up to $10 million more, but only if ESI received FDA approval by a certain date. Pet. App. at 7a, 257a-258a. Schering agreed, believing that ESI would *not* get its drug approved,[3] and that Schering would never have to pay the additional $10 million. *Id.* Judge Rueter asked the parties to write up the settlement terms and sign them that night. Pet. App. at 258a. It is undisputed that Judge Rueter was present at the preparation and signing of that January 23, 1998 handwritten agreement, and was aware of all the terms, including the payments from Schering to ESI. Pet. App. at 7a.

3. The FTC Complaint and the Trial

In April 2001, the Commission filed an administrative complaint alleging that Schering's two patent-litigation settlements restrained trade in violation of the antitrust laws.

The Upsher-Smith Settlement: the Fair-Value Issue

The ALJ appointed by the Commission presided over a ten-week trial that included dozens of witnesses and thousands of documents admitted into evidence. The central fact issue at trial was whether the Upsher-Smith settlement contained a net "payment" from Schering to Upsher-Smith, or whether Schering's $60 million payment was a *bona fide* fair-value payment for Niacor-SR and the rights to the other Upsher-Smith products. The Commission had conceded that if Schering's $60 million payment was fair value for all those

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[3] Schering had recently learned that the FDA had twice rejected ESI's clinical studies, and ESI was just beginning to re-do them. Pet. App. at 253a-254a.

rights, the Upsher-Smith settlement was lawful. Pet. App. at 92a. ("Complaint Counsel have conceded that there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the $60 million payment from Schering to Upsher.").

The Schering employees who had evaluated Niacor-SR testified and were cross-examined fully at trial. They were unaware of the patent litigation when they conducted their evaluation. Pet. App. at 22a, 191a, 319a. They were well qualified for the task. Pet. App. at 217a-219a, 319a. They had access to the results of Upsher-Smith's pivotal clinical trials for Niacor-SR. Pet. App. at 221a. And they testified that, in their best business judgment, the rights to Niacor-SR were worth more than $60 million. *See* Pet. App. at 227a-228a. Their testimony was supported by contemporaneous documents showing that they had projected Niacor-SR sales to exceed $100 million per year starting in its third year on the market, bringing Schering a profit stream with a net present value of $225-$265 million. Pet. App. at 224a-225a, 227a, 319a-320a.

Their testimony was also powerfully corroborated by testimony that another team within Schering had earlier evaluated another similar sustained-release niacin product, and had developed written sales projections for that product that were closely comparable to the Niacor-SR sales projections. Pet. App. at 6a, 22a, 111a, 115a, 209a, 213a, 318a. In addition, Schering called an independent pharmaceutical licensing expert who testified that Schering could have paid as much as $100 million for Niacor-SR (i.e., $40 million more than Schering paid for Niacor-SR *and* the bundle of other product licenses) and still made a substantial return based on the expert's "conservative" estimate of Niacor-SR's projected economic value. Pet. App. at 227a-228a.

Schering also introduced the testimony of independent members of its Board of Directors. Those directors testified that the Board had been asked to evaluate the Niacor-SR license (along with the bundle of other product licenses) *as a stand-alone deal*, and to approve the licenses only if they were sufficiently valuable to Schering, separate and apart from the settlement agreement. Pet. App. at 197a-198a. The Board concluded that they were, based on Schering's internal evaluation described above, and approved the payment for the licenses. Pet. App. at 199a. The Board was not asked to approve the settlement.[4]

By contrast, the Commission, in its case in chief, presented no fact witnesses on the valuation issue. Instead, the Commission's trial counsel relied solely on the testimony of one expert witness with experience in valuing rights to pharmaceutical products. Pet. App. at 320a. That expert's testimony was so badly discredited on cross-examination, however, that neither the ALJ *nor the Commission* relied on it. *See* Pet. App. at 130a, 320a-321a. The Commission again affirmatively disclaims any reliance on that expert in its petition. Pet. at 27.

The Upsher-Smith Settlement: the Antitrust Issue

The Commission presented an economic expert who testified that, as a matter of theory, a settlement with a payment necessarily would deliver less competition than

[4] The petition asserts that Schering's presentation to its Board of Directors "explained that the payments represented lost revenue for the period Upsher stayed off the market." Pet. at 28 n.26. In fact, the presentation to the Board specifically informed the Board that Schering told Upsher-Smith "that any such deal should stand on its own merit independent of the settlement." Pet. App. at 198a. Schering's Board members testified expressly that they understood they were to evaluate the Niacor-SR license (and the bundle of other licenses) as a stand-alone deal, and that they did so. Pet App. at 199a.

continued litigation. Pet. App. at 75a-77a. In response, Schering called its own expert economist who testified that the Commission's theory was wrong; and that in order to determine whether a particular settlement is anticompetitive it is necessary to evaluate the strength of the underlying patent case. Pet. App. at 87a-89a.

Schering then introduced the expert testimony of an experienced patent litigator who had evaluated the objective strength of Schering's positions in both the Upsher-Smith and ESI patent cases. He testified that Schering's patent was valid and infringed; that Schering likely would have won both cases; and that the settlements reasonably reflected the strength of Schering's position in each case. *See* Pet. App. at 27a.[5]

The ESI Settlement

With regard to the ESI settlement, the Commission introduced almost no proof at all. The Commission called no fact witnesses to testify at trial about the ESI settlement, and the Commission's economic expert testified about the ESI case for only about fifteen minutes. Pet. App. at 261a. In its case, Schering presented expert testimony by an experienced patent litigator that Schering's patent case against ESI was very strong, and that the settlement's January 1, 2004 entry date reasonably reflected Schering's strong case. *See* Pet. App. at 27a. The Commission's trial counsel hired its own patent-litigator expert to review the record in the ESI patent case, *but he never testified about it*.

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[5] The Commission called its own patent-litigator expert. He testified about the Upsher-Smith patent case, but not about the ESI case. The Commission's opinion never mentions either Schering's or its own expert's testimony regarding the patent case.

4. The Decisions

The ALJ found that Schering's witnesses on the valuation issue were "credible and unrebutted," and that the Commission's trial counsel had failed to satisfy its conceded burden of proving that Schering's $60 million payment to Upsher-Smith was not a *bona fide*, fair-value payment for Niacor-SR (and the bundle of other products). Pet. App. at 316a-318a, 325a-326a, 340a. The ALJ also found that the Commission had failed to prove that either settlement yielded less competition than litigation or any available alternative settlement would have yielded. Pet. App. at 310a-311a. Accordingly, the ALJ dismissed the complaint in its entirety.

The Commission reversed. It found that the rights to Niacor-SR and other products were not "adequate" consideration for Schering's $60 million payment, thus refusing to credit the testimony of Schering's and Upsher-Smith's employees and Schering's expert witness on valuation. Pet. App. at 55a.[6] The Commission declined to credit this testimony even though (1) the Commission's staff had presented no fact witness to testify about the value of Niacor-SR; (2) the Commission had no expert testimony on the valuation issue to rely on; (3) the Commission did not observe any of the witnesses whose testimony it refused to believe; and (4) the Commission has no expertise of its own in valuing pharmaceutical products.[7]

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[6] The petition similarly disregards evidence that even the Commission's opinion acknowledged. For example, the petition baldly states that Upsher-Smith demanded a payment "to stay off the market," Pet. at 7, but even the Commission's opinion admits that from the outset Upsher-Smith sought a payment *and* early entry. Pet. App. at 97a.

[7] The author of the Commission's opinion has conceded that the Commission has no expertise in valuing licensing opportunities in the pharmaceutical industry: "[H]ow do we know whether the intellectual property acquired by the pioneer is genuinely worth the money paid or

Having overruled its own ALJ and concluded that there was a net "payment" from Schering to Upsher-Smith (i.e., a payment in excess of fair market value for Niacor-SR and the other Upsher-Smith licenses), the Commission turned to its antitrust analysis. First, it concluded that the "payments" did not render the settlements either *per se* violations of the antitrust laws, or "inherently suspect." Pet. App. at 80a. The Commission explicitly endorsed a rule of reason analysis. Pet. App. at 54a-55a. It did so because Schering has a patent, giving it the lawful right to exclude competitors from the market. Therefore, the Commission undertook to compare the exclusionary impact of the agreements with the lawful exclusionary effect of the patent. Pet. at 9.

However, the Commission explicitly declined directly to evaluate the exclusionary power of Schering's patent. Instead, the Commission concluded as a matter of theory that a payment would likely render the settlement agreement anticompetitive. Pet. App. at 76a-77a. The Commission treated the "payments" as shifting the burden to Schering and Upsher-Smith to prove that the settlements were not anticompetitive. Pet. App. at 90a-91a. But in its opinion, the Commission never considered, or even mentioned, the evidence placed in the record by Schering that presumably would have addressed any burden Schering might have had; namely, the proof comparing the strength of Schering's patent case with the compromise entry dates in the settlement agreements.

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whether the whole side deal is simply a roundabout way of making otherwise suspect reverse payments? The difficulty here, of course, is similar to the difficulty the Commission would face in evaluating the merits of a patent dispute, a subject discussed above: the fact that we are not very well equipped to place a value on intellectual property." Commissioner Thomas B. Leary, "Antitrust Issues in the Settlement of Pharmaceutical Disputes, Part II," May 17, 2001 at 6.

A panel of the Court of Appeals for the Eleventh Circuit unanimously set aside the Commission's opinion and vacated its Order. After a thorough review of the whole record under the "substantial evidence" standard, the Court of Appeals found that the Commission's finding of fact on the valuation issue was not supported by substantial evidence. The Court of Appeals also faulted the Commission's almost exclusive reliance on the purported existence of a payment as the basis for its conclusion that the patent-litigation settlements were anticompetitive. Instead, the Court of Appeals held that a factual inquiry into the exclusionary power of Schering's patent was required. Because the Commission failed to engage in such an inquiry, the Court of Appeals set aside the Commission's Opinion. Pet. App. at 34a-35a.

REASONS FOR DENYING THE WRIT

The petition should be denied for the following reasons.

1. The Commission Lost the Schering/Upsher-Smith Case on a Dispositive Threshold Issue of Fact.

The great majority of the trial of this case was devoted to the question whether the $60 million payment from Schering to Upsher-Smith was fair value for the rights to Niacor-SR and the other products. The Commission conceded in its opinion that its entire legal analysis hinged on this "critical valuation issue." Pet. App. at 92a. And the Commission's staff had conceded at trial that "there is no liability in this matter if the licenses that Upsher granted to Schering were adequate consideration for the $60 million payment from Schering to Upsher." Pet. App. at 92a.

After a full trial on the fair value issue, the Commission's ALJ determined that the Respondents' "fact testimony . . . was unrebutted and credible in establishing that the licensing agreement was a bona fide arms-length transaction." Pet. App. at 317a-318a. And the Court of Appeals found that the Commission's contrary finding of fact on its *de novo* review of the record was unsupported by any substantial evidence.

The finding by the Court of Appeals is on a pure issue of fact with significance to this case and this case only. It disposes of the Commission's challenge to the Schering/Upsher-Smith settlement, and there is no reason to review it.

2. The Schering/ESI Settlement Does Not Warrant Review.

The Commission's half-hearted challenge to the Schering/ESI settlement also does not warrant review. The Commission itself conceded in its own opinion that, with respect to the ESI settlement, "as a matter of prosecutorial discretion, we might not have brought a stand alone case based on such relatively limited evidence." Pet. App. at 145a.

The evidence that *was* introduced showed that the settlement resulted from fifteen months of court-supervised mediation. The small payment was needed to break an impasse in the negotiations, and it was urged on the parties by the U.S. Magistrate Judge as a way of resolving the case. The resulting settlement was fair to consumers as well as to the parties: the unrebutted evidence showed that the compromise entry date fairly reflected the strength of Schering's patent case. Under a rule of reason analysis—which the Commission says is the appropriate analysis—the

ESI settlement presents only a fact-specific case correctly resolved by the Court of Appeals.

3. The Court of Appeals Did Not Misapply the Standard of Review of Agency Fact Finding; and in Any Event the Misapplication of a "Properly Stated Rule of Law" Does Not Warrant Certiorari.

It is undisputed that the Court of Appeals properly stated the standard that courts of appeals must follow when reviewing agency fact finding. Thus, the Court of Appeals explained that:

> The FTC's findings of fact, "if supported by evidence, shall be conclusive." *This standard applies regardless whether the FTC agrees with the ALJ.* (emphasis added).

The Court of Appeals continued:

> *We are mindful that we do not review the record to draw our own conclusions* that we then measure against an administrative agency; rather, we must consider *all* of the evidence when drawing our conclusions about the reasonableness of an agency's findings of fact. The evidence must be such that it would be possible for a reviewing court to reach the same conclusions that the administrative fact-finder did. If this condition is not met, then the substantial evidence test requires that the administrative decision be reversed.

Pet. App. at 10a-12a (internal citations omitted) (emphasis added).

The Commission makes no claim that the Court of Appeals misstated the standard of review. Rather, the Commission complains that the Court of Appeals attached some weight to the ALJ's credibility determinations. But that is exactly what this Court has held a reviewing court of appeals ought to do. Thus, in *Universal Camera v. NLRB*, 340 U.S. 474, 496 (1950), this Court stated:

> [E]vidence supporting a conclusion [by the agency] may be less substantial when an impartial, experienced examiner who has *observed the witnesses and lived with the case* has drawn conclusions different from the [agency's] than when he has reached the same conclusion. (emphasis added).

And this Court continued,

> The significance of [the examiner's] report, of course, depends largely on the *importance of credibility* in the particular case.

Universal Camera, 340 U.S. at 496 (emphasis added).[8]

Credibility was very important in this case. If Respondents' witnesses on the valuation issue—who testified fully at trial—were believed, the Commission's challenge to the Upsher-Smith settlement would fail.

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[8] The Commission's petition omits any reference to these parts of the *Universal Camera* opinion.

In its opinion, the Court of Appeals correctly stated the applicable standard of review. The Commission is thus left to complain—with little or no basis—only that the Court of Appeals *misapplied* that standard in this particular case. Respondents strongly disagree. However, in either event, this Court's rules state that "a petition for certiorari is rarely granted when the asserted error consists of . . . misapplication of a properly stated rule of law." SUP. CT. R. 10.[9] This case is not one of those rare instances.

4. The Petition Overstates the Difference in Antitrust Analysis Between the Court of Appeals and the Commission.

The Commission overstates the extent to which the Court of Appeals' antitrust analysis differs from its own. There is indeed much common ground.

An agreement determining a potential competitor's entry into the market would be illegal *per se* if there were no patent. Both the Commission and the Court of Appeals agree about this. As the Commission explains: "The starting point for this case, as the court of appeals recognized, is that an agreement between competitors in which one pays the other to stay out of a market is 'clearly anticompetitive,' and hence unlawful *unless excused by the lawful exercise of patent rights*." *See* Pet. at 13 (emphasis added). Similarly, the Court of Appeals explained that, if not for a patent, an

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[9] The Commission also complains that the Court of Appeals did not afford sufficient "deference" to the Commission's expertise. Pet. at 29. But the critical fact issue in this case was the valuation of Niacor-SR, a pharmaceutical product. And as noted above, the Commission has no expertise in valuing pharmaceutical products. This proposition was acknowledged by the author of the Commission's opinion, Commissioner Thomas B. Leary. *See supra* n.7.

agreement to allocate markets is "clearly anticompetitive." Pet. App. at 13a.

The Commission and the Court of Appeals also agree that a payment—if proved—would not make these settlements subject to *per se* treatment, because of the existence of Schering's patent. Pet. at 9. Thus, the Commission explains that it "determined that per se condemnation was not warranted, given the complexities of the patent litigation context in which the agreements arose." *Id.* Similarly, the Court of Appeals explained: "In the context of patent litigation . . . the anticompetitive effect [of the agreement] may be no more broad than the patent's own exclusionary power." Pet. App. at 13a.

Finally, the Commission and the Court of Appeals agree that the appropriate antitrust analysis must involve a comparison of the exclusionary effect of the settlement with the lawful exclusionary power of Schering's patent. As the Commission states, it believes it should conduct precisely such an analysis in this case, comparing "the exclusionary impact of the agreements in relation to that of the patent itself." Pet. at 9. Similarly, the Court of Appeals explained that it was comparing "(1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreement exceeds the scope; and (3) the resulting anticompetitive effects." Pet. App. at 17a.[10]

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[10] The Commission describes the Court of Appeals' statement that the court would apply neither traditional rule of reason nor *per se* analysis as a "startling premise," Pet. at 11, and suggests that this is a sharp point of difference between the Commission's approach and the Court of Appeals'. It is not. If anything, it is a difference in label, not analysis. The Court of Appeals' point is that a traditional rule of reason analysis would examine solely the market effects of generic entry. That, however, is not the pertinent inquiry here. Everyone already knows that generic entry will bring lower prices. *See, e.g., Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003), *cert. denied*

Officials of the Antitrust Division of the U.S. Department of Justice have similarly rejected *per se* treatment for patent settlement payments because of the importance of the exclusionary power of patents. For example, in 2003, the then-Acting Assistant Attorney General for the Antitrust Division explained:

> [A]ssessing the competitive significance of settlements often depends on an evaluation of the underlying strength of patent rights. If a patent is valid and infringed, then any competitive entry allowed by a settlement is up to the patent holder. If a patent is invalid or not infringed, then there should be no impediment to competitive entry whatsoever. The problem is that we have no way definitively to know which situation applies *without evaluating the underlying IP rights*, a task that is outside our core expertise as antitrust enforcers.[11]

Then-Assistant Attorney General Pate reiterated this view in a recent speech. Noting the fact that the Court of Appeals *in this case* had ruled just "months ago," Mr. Pate explained that antitrust liability is difficult to assess:

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sub nom. Walgreen Co. v. Abbott Labs., No. 03-1178 (Oct. 12, 2004). The important inquiry here, according to the Court of Appeals, is whether the settlement agreement's exclusionary effects exceed the legitimate exclusionary power of the patent. *See* Pet. App. at 16a; *Valley Drug*, at 344 F.2d 1294, 1311 n.27. The Commission accepts this as the relevant inquiry, stating that it "considered the exclusionary impact of the agreements in relation to that of the patent itself." Pet. at 9. The Commission calls this inquiry a rule of reason inquiry, and the Court of Appeals does not. But it is the same inquiry.

[11] R. Hewitt Pate, Acting Assistant Attorney General, Antitrust Division, "*Antitrust and Intellectual Property*," January 24, 2003 (emphasis added).

> unless one knows whether the patent owner could have won an infringement claim. If the patent is valid, all entry before its expiration is a competitive "gift," but if it is invalid, any delay in entry due to threatened patent enforcement is a competitive harm.[12]

District courts have expressed similar views. *See, e.g., Asahi Glass Co. Ltd. v. Pentech Pharmaceuticals, Inc.*, 289 F.Supp.2d 986, 994 (N.D. Ill. 2003) (Posner, J. sitting by designation) (doubting correctness of theory that payments render settlements anticompetitive regardless of patent merits because "if settlement negotiations fell through and the patentee went on to win his suit, competition would be prevented to the same extent"); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514, 540 (E.D.N.Y. 2005) (settlement with payments not anticompetitive if within scope of patent claims).

Thus, the Commission, the Court of Appeals and the Department of Justice agree on the basic framework for analyzing settlements of patent infringement suits that include payments. The problem in this case, however, arose when the Commission *implemented* that framework.

In its opinion in this case, the Commission relied solely on the purported fact of a payment, finding that the payment meant, as a matter of theory, that the settlement was anticompetitive. Pet. App. at 76a-77a ("[I]t is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.").

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[12] R. Hewitt Pate, Assistant Attorney General, Antitrust Division, *"Competition and Intellectual Property in the U.S.: Licensing Freedom and the Limits of Antitrust,"* June 3, 2005.

The Commission then shifted the burden to Schering and Upsher-Smith to prove that the settlements were not anticompetitive. Pet. App. at 90a-91a. But the Commission ignored the proof Respondents had placed in the record to meet that burden: proof comparing the strength of Schering's patent case to the compromise entry dates in the settlement agreements.

The problem, thus, was that the Commission's implementation of its announced rule of reason framework turned out in practice to be no different from the *per se* rule it purported to reject.

5. The Commission's Statements About the Real World Dangers of Patent Settlement Are Suspect.

The Commission does not assert that there is any conflict among the circuits on the issues presented by this case. The Commission states that the Sixth Circuit's decision in *In re Cardizem CD Antitrust Litigation*, 332 F.3d 896, 908 (6th Cir. 2003), *cert. denied sub nom. Andrx Pharms., Inc. v. Kroger Co.*, No. 03-799 (October 12, 2004), represents a "different approach" from that of the Eleventh Circuit in this case, but the Commission expressly disagrees with the Sixth Circuit's approach. Pet. at 23. Moreover, as the Commission told this Court a year ago, there is no "square conflict" between the circuits because of dispositive factual differences between the *Cardizem/Andrx* case and the Eleventh Circuit's decision in a similar pharmaceutical patent case, *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003).[13] *Brief of United States as Amicus Curiae Opposing the Petition in Cardizem/Andrx*, 2004 WL

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[13] The Court of Appeals' decision in this case expressly follows its prior *Valley Drug* decision. Pet. App. at 12a-17a.

1562075 (July 2004), at *11. Nothing has changed in that regard.

Furthermore, the Commission and the Solicitor General urged in their opposition to certiorari last term in *Cardizem/Andrx* that "[s]ettlements with reverse payments in an amount far exceeding litigation costs . . . appear to be rare outside the Hatch-Waxman context;" and that Congress' 2003 Amendments to the Hatch-Waxman Act reduced the risk of anticompetitive settlements in the pharmaceutical arena. *See* U.S. Br., 2004 WL 1562075, at *15-*19. Accordingly, the Commission urged that certiorari was not warranted.

The Commission and the Solicitor General also noted that Congress' 2003 amendments to Hatch-Waxman requiring mandatory review of all pharmaceutical patent-litigation settlements by the antitrust agencies counseled against certiorari in *Cardizem/Andrx*. The Commission's first annual report on this mandatory review of such settlements, published in January 2005, substantiates this view. Thus, the Commission states: "legitimate patent settlements continue to occur without hindrance from the Commission decision, using means other than payments by the patent holders to reach a compromise." Pet. at 22. Indeed, the Commission's January 2005 report goes further in stating that settlements involving payments to the alleged infringer are not a pressing issue:

> The structure of brand-generic settlements has changed over time in that *settlements after 1999 do not appear to include a payment from the brand to the generic in exchange for the generic's agreement not to market its product*. . . . In 1999, it was reported that the Federal Trade Commission was investigating agreements involving such

> payments. *Since that time, the Commission is aware of no final settlements of patent litigation in the pharmaceutical industry in which the brand paid the generic to agree not to market its product.*[14]

It may well be that the Commission's actions in this case and others have had an *in terrorem* effect on subsequent settlements.

Despite its January 2005 report, the Commission speculates that future settlements may nonetheless raise antitrust concerns, and absent this Court's review, "any substantial pharmaceutical company involved in a further case of this sort could presumably obtain review in the Eleventh Circuit to take advantage of the ruling below without running the risk of a conflicting ruling from another circuit." Pet. at 24. The Commission's conjecture is unfounded, however. First, the Commission is free to bring an action in any district court in which a pharmaceutical company conducts business. 15 U.S.C. § 45(m) (2005). Second, private plaintiffs may also bring suit against pharmaceutical companies in any district in which such pharmaceutical company conducts business. 28 U.S.C. §1391(b) (2005). Third, the Commission could bring its cases in a manner consistent with the Eleventh Circuit's decision. A recent decision by the Eleventh Circuit shows that its decision in this case does not portend the death-knell of antitrust cases against pharmaceutical patent settlements, as the Commission speculates. *See Andrx Pharmaceuticals,*

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[14] Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2004—A Report by the Bureau of Competition* (Jan. 7, 2005), <www.ftc.gov/os/2005/01/050107medicareactrpt.pdf> [§ II.B] (emphasis added).

Inc. v. Elan Corp., et al., __ F.3d __, 2005 WL 2061009 (11th Cir. Aug. 29, 2005) (refusing to dismiss antitrust complaint against pharmaceutical patent settlement: complaint successfully plead antitrust violation consistent with the Court of Appeals' *Schering-Plough* decision).

Finally, the Commission asserts that this Court's review is necessary because the Court of Appeals' decision will thwart congressional policy to encourage entry of generic pharmaceuticals. As the Commission concedes, however, the Hatch-Waxman Act attempts to balance its goal of encouraging generic entry with an equally important goal of "fully protecting legitimate patent claims." Pet. at 3. The Court of Appeals' decision in this case accommodates this balance. For example, Schering's settlement with Upsher-Smith split the remaining life of Schering's patent in half, and allowed generic entry five years *before* the expiration of Schering's patent. Without comparing the settlement to the exclusionary potential of Schering's patent, it is impossible to know whether generic entry was delayed or accelerated. In fact, the evidence adduced at trial established that, based on the strength of Schering's patent case, entry was likely accelerated.

As the Commission argued a year ago, this Court's review is not warranted. Nothing has changed to alter that conclusion.

CONCLUSION

For all of the foregoing reasons, the petition should be denied.

Respectfully submitted,

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No. ___

IN THE

Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,

v.

SCHERING-PLOUGH CORPORATION, *et al.*

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

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APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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APPENDIX A

[PUBLISH]

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 04-10688

Agency No. FTC 9297

SCHERING-PLOUGH CORPORATION,
UPSHER-SMITH LABORATORIES, INC.,
A MINNESOTA CORPORATION HAVING ITS PRINCIPAL
PLACE OF BUSINESS IN MINNESOTA,
PETITIONERS,

VERSUS

FEDERAL TRADE COMMISSION,
RESPONDENT.

Petitions for Review of a Decision of the
Federal Trade Commission

(March 8, 2005)

Before DUBINA and FAY, Circuit Judges, and
GOLDBERG *, Judge.

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* Honorable Richard W. Goldberg, Judge, United States Court of International Trade, sitting by designation.

FAY, Circuit Judge:

Pharmaceutical companies Schering-Plough Corp. and Upsher-Smith Laboratories, Inc. petition for review of an order of the Federal Trade Commission ("FTC") that they cease and desist from being parties to any agreement settling a patent infringement lawsuit, in which a generic manufacturer either (1) receives anything of value; and (2) agrees to suspend research, development, manufacture, marketing, or sales of its product for any period of time. The issue is whether substantial evidence supports the conclusion that the Schering-Plough settlements unreasonably restrain trade in violation of Section 1 of the Sherman Antitrust Act, 15 U.S.C. § 1, and Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(c). We have jurisdiction pursuant to 15 U.S.C. § 45(c), and, for the reasons discussed below, we grant the petition for review and set aside and vacate the FTC's order.

I. Factual Background

A. The Upsher Settlement

Schering-Plough ("Schering") is a pharmaceutical corporation that develops, markets, and sells a variety of science-based medicines, including antihistamines, corticosteroids, antibiotics, anti-infectives and antiviral products. Schering manufactures and markets an extended-release microencapsulated potassium chloride product, K-Dur 20,which is a supplement generally taken in conjunction with prescription medicines for the treatment of high blood pressure or congestive heart disease. The active ingredient in K-Dur 20, potassium chloride, is commonly used and unpatentable. Schering, however, owns a formulation patent on the extended-release coating, which surrounds the potassium chloride in K-

Dur 20, patent number 4,863,743 (the "'743 patent"). The '743 patent expires on September 5, 2006.[1]

In late 1995, Upsher-Smith Laboratories ("Upsher"), one of Schering's competitors, sought Food and Drug Administration ("FDA") approval to market Klor Con M20 ("Klor Con"), a generic version of K-Dur 20.[2] Asserting that Upsher's product

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[1] Schering also markets another version of this product, K-Dur 10, the coating of which is also covered by the '743 patent. The difference between the two is dosage: K-Dur 20 contains twice as much potassium as K-Dur 10. This lawsuit only involves K-Dur 20.

The '743 patent claims a pharmaceutical dosage unit in tablet form for oral administration of potassium chloride. The tablet contains potassium chloride crystals coated with a cellulose-type material. The novel feature in the '743 patent is the viscous coating, which is applied to potassium chloride crystals. The coating provides a sustained-release delivery of the potassium chloride.

[2] The FDA must approve any new drug before it can be marketed or sold in the United States. Previously, applications for FDA approval proceeded under a new drug application ("NDA"). 21 U.S.C. § 355(b). This cumbersome and involved process required each applicant to submit safety and efficacy studies, even if it duplicated previous studies done on identical drugs with the same ingredients. In 1984, Congress passed Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), Pub.L. No. 98-417, 98 Stat. 1585 (1984). The purpose of the Hatch-Waxman Act was threefold: (1) to reduce the average price paid by consumers; (2) preserve the technologies pioneered by the brand-name pharmaceutical companies; and (3) create an abbreviated new drug application ("ANDA") to bring generic drugs to the market.

The ANDA process allows the manufacturers of generic drugs to gain early entry into the market. Hatch-Waxman's truncated procedure avoids the duplication of expensive safety and efficacy studies, so long as the generic manufacturer proves that its drug is bio-equivalent to the already-approved brand-name/pioneer drug. As part of the application process, the generic applicant must certify that the relevant patent(s) on the brand-name drug are either invalid or will not be infringed. This is commonly known as a "Paragraph IV certification." The patent holder is then notified of the ANDA, and if the patent holder sues for infringement within forty-five days of receiving the notice, the FDA automatically institutes a thirty-month delay on the generic manufacturer's ANDA approval. See 21 U.S.C. 355(j)(5)(B)(iii).

was an infringing generic substitute, Schering sued for patent infringement. K-Dur 20 itself was the most frequently prescribed potassium supplement, and generic manufacturers such as Upsher could develop their own potassium-chloride supplement as long as the supplement's coating did not infringe on Schering's patent.

In 1997, prior to trial, Schering and Upsher entered settlement discussions. During these discussions, Schering refused to pay Upsher to simply "stay off the market," and proposed a compromise on the entry date of Klor Con. Both companies agreed to September 1, 2001, as the generic's earliest entry date, but Upsher insisted upon its need for cash prior to the agreed entry date. Although still opposed to paying Upsher for holding Klor Con's release date, Schering agreed to a separate deal to license other Upsher products. Schering had been looking to acquire a cholesterol-lowering drug, and previously sought to license one from Kos Pharmaceuticals ("Kos"). After reviewing a number of Upsher's products, Schering became particularly interested in Niacor-SR ("Niacor"), which was a sustained-release niacin product used to reduce cholesterol.[3]

Upsher offered to sell Schering an exclusive license to market Niacor worldwide, except for North America. The parties executed a confidentiality agreement in June 1997, and Schering received licenses to market five Upsher products, including Niacor. In relation to Niacor, Schering received a data package, containing the results of Niacor's clinical studies.

As part of its ANDA, Upsher certified that Schering's patent was either invalid or that Upsher did not infringe on that patent. When Schering brought suit, the thirty-month delay was activated.

[3] Schering's focus on Niacor is consistent with its previous attempt to purchase the rights to Niaspan, another sustained-release niacin product, which Kos was in the process of developing during this time. Negotiations between Kos and Schering broke down several months before Upsher offered Niacor to Schering.

The cardiovascular products unit of Schering's Global Marketing division, headed by James Audibert ("Audibert") evaluated Niacor's profitability and effectiveness.

According to the National Institute of Health, niacin was the only product known to have a positive effect on the four lipids related to cholesterol management. Immediate-release niacin, however, created an annoying – but innocuous – side effect of "flushing," which reduced patient compliance. On the other hand, previous versions of sustained-release niacin supplements, like Niacor, had been associated with substantial elevations in liver enzyme levels.

Schering knew of the effects associated with niacin supplements, but continued with its studies of Niacor because it had passed the FDA's medical review and determined that it would likely be approved. More important, the clinical trials studied by Audibert demonstrated that Niacor reduced the flushing effect to one-fourth of the immediate-release niacin levels and only increased liver enzymes by four percent, which was generally consistent with other cholesterol inhibitors. Based on this data, Audibert constructed a sales and profitability forecast, and concluded that Niacor's net present value at that time would be between $245-265 million.

On June 17, 1997, the day before the patent trial was scheduled to begin, Schering and Upsher concluded the settlement. The companies negotiated a three-part license deal, which called for Schering to pay (1) $60 million in initial royalty fees; (2) $10 million in milestone royalty payments; and (3) 10% or 15% royalties on sales. Schering's board approved of the licensing transaction after determining the deal was valuable to Schering. This estimation corresponds to the independent valuation that Schering completed in relation to Kos' Niaspan, a substantially similar product to Niacor. That evaluation fixed Niaspan's net present value between $225-265 million.

The sales projections for both the Kos and Upsher products are substantially similar. Raymond Russo ("Russo") estimated Niaspan (Kos' supplement) sales to reach $174 million by 2005 for the U.S. market. Comparably, and more conseratively, Audibert predicted Niacor (Upsher's supplement) to reach $136 million for the global market outside the United States, Canada, and Mexico, which is either equal to or larger than U.S. market alone.[4]

After acquiring the licensing rights to Niacor, Schering began to ready its documents for overseas filings. In late 1997, however, Kos released its first-quarter sales results for Niaspan, which indicated a poor performance and lagging sales. Following this announcement, Kos' stock price dramatically dropped from $30.94 to $16.56, and eventually bottomed out at less than $6.00. In 1998, with Niaspan's disappointing decline as a precursor, Upsher and Schering decided further investment in Niacor would be unwise.

B. The ESI Settlement

In 1995, ESI Lederle, Inc. ("ESI"), another pharmaceutical manufacturer, sought FDA approval to market its own generic version of K-Dur 20 called "Micro-K 20."[5] Schering sued ESI in United States District Court, and, as part of the pretrial process, the trial judge prompted the parties to engage a court-supervised mediation, pursuant to the Civil Justice Reform Act, 28 U.S.C. § 471 et seq. (1991). The trial court appointed U.S.

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[4] Indeed, there is the indication of some internal independence between Schering's evaluation of Niaspan and Niacor, as two different teams examined the products and arrived at similar estimates.

[5] On December 22, 1995, ESI submitted an ANDA to the FDA that reference K-Dur 20 and contained a Paragraph IV certification to Schering's '743 patent. On December 29, 1995, ESI notified Schering of this certification containing data from a study demonstrating Micro-K 20's bioequivalency to Schering's K-Dur 20's tablets.

Magistrate Judge Thomas Rueter ("Judge Rueter") to mediate the fifteen-month process, which resulted in nothing more than an impasse.

Finally, in December 1997, Schering offered to divide the remaining patent life with ESI and allow Micro-K 20 to enter the market on January 1, 2004 – almost three years ahead of the patent's September 2006 expiration date.[6] ESI accepted this offer, but demanded on receiving some form of payment to settle the case. At Judge Rueter's suggestion, Schering offered to pay ESI $5 million, which was attributed to legal fees, however, ESI insisted upon another $10 million. Judge Rueter and Schering then devised an amicable settlement whereby Schering would pay ESI up to $10 million if ESI received FDA approval by a certain date. Schering doubted the likelihood of this contingency happening, and Judge Rueter intimated that if Schering's prediction proved true, it would not have to pay the $10 million.[7] The settlement was signed in Judge Rueter's presence on January 23, 1998.[8]

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[6] There was also a side agreement in this settlement that provided for a payment of $15 million in return for the right to license generic enalpril and buspirone from ESI..

[7] ESI provided Schering with information related to the Micro-K 20's current approval status. The summary noted the difficulties ESI had up to that point in trying to obtain FDA approval for its proposed generic version. The primary concern was ESI's bioequivalence study, which had been performed in 1989. The FDA found five different deficiencies with regard to that study, and ESI did not respond to those deficiencies until May 1997. ESI then began a new bioequivalence study in December 1997.

[8] Under the final settlement agreement, dated June 19, 1998, Schering agreed to pay ESI a $5 million noncontingent payment, representing legal fees, and an additional $10 million contingent on ESI's FDA approval. Schering and ESI also entered into a contemporaneous license agreement whereby ESI granted Schering the licenses to enalpril and buspirone in exchange for $15 million.

C. The FTC Complaint

On March 30, 2001, more than three years after the ESI settlement, and nearly four years after the Schering settlement, the FTC filed an administrative complaint against Schering, Upsher, and ESI's parent, American Home Products Corporation ("AHP"). The complaint alleged that Schering's settlements with Upsher and ESI were illegal agreements in restraint of trade, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The complaint also charged that Schering monopolized and conspired to monopolize the potassium supplement market.[9]

II. Procedural History

The Complaint was tried before an Administrative Law Judge (ALJ) from January 23, 2002 to March 28, 2002. Numerous exhibits were admitted in evidence, and the ALJ heard testimony from an array of expert witnesses presented by both sides. In his initial decision, the ALJ found that both agreements were lawful settlements of legitimate patent lawsuits, and dismissed the complaint. Specifically, the ALJ ruled that the theories advanced by the FTC, namely, that the agreements were anticompetitive, required either a presumption of (1) that Schering's '743 patent was invalid; or (2) that Upsher's or ESI's generic products did not infringe the '743 patent. The ALJ concluded that such presumptions had no basis in law or fact. Moreover, the ALJ noted that Schering's

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[9] On October 12, 2001, the Complaint against AHP was withdrawn to consider a proposed consent agreement. The FTC approved a final consent order on April 2, 2002. AHP was not a party to either the trial before the ALJ or any subsequent proceedings, and is not a party to this appeal. The legality of the Schering's settlement with ESI/AHP, however, remained at issue with respect to Schering.

witnesses went unrebutted by FTC complaint counsel, and credibly established that the licensing agreement with Upsher was a "bona-fide arm's length transaction."

The ALJ further found that the presence of payments did not make the settlement anticompetitive, per se. Rather, the strength of the patent itself and its exclusionary power needed to be assessed. The initial decision highlighted the FTC's failure to prove that, absent a payment, either better settlement agreements or litigation results would have effected an earlier entry date for the generics. Finally, the ALJ found no proof that Schering maintained an illegal monopoly within the relevant potassium chloride supplement market.

The FTC's complaint counsel appealed this decision to the full Commission. On December 8, 2003, the Commission issued its opinion, reversing the ALJ's initial decision, and agreeing with complaint counsel that Schering's settlements with ESI and Upsher had violated the FTC Act and the Sherman Act. Although it refrained from ruling that Schering's payments to Upsher and ESI made the settlements per se illegal, the Commission concluded that the quid pro quo for the payment was an agreement to defer the entry dates, and that such delay would injure competition and consumers.

In contrast to the ALJ's inquiry into the merits of the '743 patent litigation, the Commission turned instead to the entry dates that "might have been" agreed upon in the absence of payments as the determinative factor. Despite the Commission's assumption that the parties could have achieved earlier entry dates via litigation or non-monetary compromises, it also acknowledged that the settled entry dates were non-negotiable. Upon review of the settlement payments, the Commission determined that neither the $60 million to Upsher nor the $30 million to ESI represented legitimate consideration for the licenses granted by Upsher or ESI's ability to secure FDA

approval of its generic.[10] Consequently, the Commission prohibited settlements under which the generic receives anything of value and agrees to defer its own research, development, production or sales activities. Nevertheless, the Commission carved out one arbitrary exception for payments to the generic: beyond a "simple compromise" to the entry date, if payments can be linked to litigation costs (not to exceed $2 million), and the Commission is notified of the settlement, then the parties need not worry about a later antitrust attack. Neither of the Schering agreements fit this caveat, and Schering and Upsher timely petition for review.

III. Standard of Review

We review the FTC's findings of fact and economic conclusions under the substantial evidence standard. 15 U.S.C. § 45(c); see Orkin Exterminating Co., Inc. v. FTC, 849 F.2d 1354 (11th Cir. 1988); Oiin Corp. v. FTC, 986 F.2d 1295 (9th Cir. 1993). The FTC's findings of fact, "if supported by evidence, shall be conclusive." 15 U.S.C. § 45(c). This standard applies regardless whether the FTC agrees with the ALJ. Thiret v. FTC, 512 F.2d 176, 179 (10th Cir. 1975). We may, however, examine the FTC's findings more closely where they differ from those of the ALJ. Id.; California Dental Association v. FTC, 128 F.3d 720, 725 (9th Cir.1997), rev'd on other grounds, 526 U.S. 756 (1990); see also ITT Continental Baking Co. v. FTC, 532 F.2d 207, 219 (2d Cir. 1976); American Cyanamid Co. v. FTC, 363 F.2d 757, 772-73 (6th Cir. 1966). "Substantial evidence is more than a mere

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[10] The contradictory nature of the Commission's opinion is exemplified by its assessment of the ESI settlement. Although the Commission found the payment to be unjustified and in violation of the law, it simultaneously explained that "[a]s a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence."